

## § 799.1645

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

[50 FR 21412, May 23, 1985; 50 FR 33543, Aug. 20, 1985; 51 FR 3468, Jan. 28, 1986; 51 FR 4736, Feb. 7, 1986; 52 FR 3238, Feb. 3, 1987; 54 FR 27356, June 29, 1989; 55 FR 3408, Feb. 1, 1990; 55 FR 7326, Mar. 1, 1990; 56 FR 23230, May 21, 1991; 58 FR 34205, June 23, 1993; 60 FR 34467, July 3, 1995]

### § 799.1645 2-Ethylhexanol.

(a) *Identification of test substance.* (1) 2-Ethylhexanol (CAS No. 104-76-7) shall be tested in accordance with this section.

(2) 2-Ethylhexanol of at least 99.0-percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture or process, or intend to manufacture or process 2-ethylhexanol, other than as an impurity, from the effective date of this final rule to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, conduct tests, and submit data or exemption applications as specified in this section, subpart A of this part, and parts 790 and 792 of this chapter for single-phase rulemaking.

(c) *Health effects—(1) Oncogenic effects—(i) Required testing.* (A) Oncogenicity tests shall be conducted in Fisher 344 rats and B6C3F1 mice by the oral route with 2-ethylhexanol in accordance with § 798.3300 of this chapter, except for the provisions in § 798.3300(b)(6).

(B) For the purpose of this section, the following provisions also apply to the oncogenicity tests: (1) *Administration of the test substance.* 2-Ethylhexanol shall be administered either by microencapsulation before adding it to the diet or by gavage.

(2) [Reserved]

(ii) *Reporting requirements.* (A) The study plan for the oncogenicity test shall be submitted at least 45 days before the initiation of testing.

(B) The oncogenicity testing shall be completed and final report submitted to the Agency within 53 months of the effective date of this final rule if 2-ethylhexanol is administered by ga-

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vage or within 56 months of the effective date of this final rule if administered by microencapsulation.

(C) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(2) [Reserved]

(d) *Effective date.* The effective date of this final rule requiring oncogenicity testing of 2-ethylhexanol is September 16, 1987.

[52 FR 28704, Aug. 3, 1987, as amended at 58 FR 34205, June 23, 1993]

### § 799.1700 Fluoroalkenes.

(a) *Identification of test substances.* (1) Vinyl fluoride (VF; CAS No. 75-02-5), vinylidene fluoride (VDF; CAS No. 75-38-7), tetrafluoroethene (TFE; CAS No. 116-14-3), and hexafluoropropene (HFP; CAS No. 116-15-4) shall be tested in accordance with this section.

(2) VF, VDF, TFE, and HFP of at least 99 percent purity shall be used as the test substances.

(b) *Persons required to submit study plans, conduct tests and submit data.* All persons who manufacture VF, VDF, TFE, or HFP, other than as an impurity, from July 22, 1987 to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests in accordance with the TSCA Good Laboratory Practice Standards (40 CFR part 792), and submit data as specified in this section, subpart A of this part, and part 790 of this chapter for single-phase rulemaking, for the substances they manufacture.

(c) *Health effects testing—(1) Mutagenic effects—Gene mutation—(i) Required testing.* (A) (1) A detection of gene mutations in somatic cells in culture assay shall be conducted with TFE and HFP in accordance with § 798.5300 of this chapter except for the provisions in paragraphs (c), (d)(3)(i), (4), (5) and (6) and (e).

(2) For the purposes of this section, the following provisions also apply:

(i) *Reference substances.* No reference substance is required.

(ii) *Test method—Type of cells used in the assay.* Mutation induction at the